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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|------------------------------------|----------------------|---------------------|------------------|
| 10/632,943 | 07/31/2003 | Scott Gilbert | ARC 3274 R1 | 4967 |
| 30766 | 7590 01/06/2006 | | EXAMINER | |
| DEWIPAT INCORPORATED | | | SCHELL, LAURA C | |
| | 60 WEST, SUITE 400, PI TX 77069 | MB 166 | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | Application No. | Applicant(s) | | | | |
|--|---|-----------------------------|--|--|--|--|
| | 10/632,943 | GILBERT, SCOTT | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Laura C. Schell | 3767 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1)⊠ Responsive to communication(s) filed on 31 Ju | Responsive to communication(s) filed on 31 July 2003. | | | | | |
| •— | • • | | | | | |
| 3) Since this application is in condition for allowan | since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-37</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5)⊠ Claim(s) <u>37</u> is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1,2,7-13,19-25 and 31-36</u> is/are reject | 6) Claim(s) 1,2,7-13,19-25 and 31-36 is/are rejected. | | | | | |
| 7)⊠ Claim(s) <u>3-6,14-18 and 26-30</u> is/are objected to | ☑ Claim(s) <u>3-6,14-18 and 26-30</u> is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9)⊠ The specification is objected to by the Examiner. | | | | | | |
| 10)⊠ The drawing(s) filed on <u>31 July 2003</u> is/are: a) accepted or b)⊠ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | (PTO-413) | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal P | atent Application (PTO-152) | | | | |
| Paper No(s)/Mail Date 1-23-04 | 6) Other: | | | | | |

DETAILED ACTION

Specification

The drawings are objected to under 37 CFR 1.83(a) because they fail to show element (46), the deflectable arms, as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The disclosure is objected to because of the following informalities: paragraph [0015] contains an erroneous phrase "of the present" on line 19 and should be deleted.

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Also, paragraph [0016] on line 16 has a phrase "the a releasable" in which "a" should be deleted. Appropriate correction is required.

The abstract of the disclosure is objected to because of the repeated phrase "the desired" on line 9. Correction is required. See MPEP § 608.01(b).

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement filed 1/23/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claims 13, 25 and 37 are objected to because of the following informalities: In reference to claim 13, line 8 appears to contain a repeated word, "within" in the phrase "within at least partially within the outer plunger" and should read "at least partially within the outer plunger". The same error also appears in claim 25 on line 4. In reference to

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claim 37, line 5 contains a spelling error "he" should be replaced as "the". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 7-12, 13, 19-24, 25 and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeffrey (US Patent No. 5,957,897) in view of Antoshkiw (US Patent No. 4,188,949). Jeffrey discloses an injection device substantially as claimed, a body (Fig. 1, 111) including a syringe cartridge (125) including a needle (120), a trigger mechanism (Fig. 2, 155), a drive mechanism (119) and a bias mechanism (123), wherein the injection device is configured to provide automatic injection of a desired dose of the medicament followed by automatic retraction of the needle associated with the syringe cartridge (col. 1, lines 53-67), as well as a drive mechanism (119) and the bias mechanism (123) both comprise a spring (141 and 123 respectively), and that the inner plunger (132) comprises a decoupling mechanism (160) formed integrally and operatively associated therewith, and that the inner plunger (132) includes a distal end (end near 130) with a sealing member (130) and piston (130) near the distal end. Jeffrey, however, does not disclose expressly a compound plunger or reservoir. Antoshkiw discloses a compound plunger (Fig. 2b, elements 12 and 13) wherein the compound plunger comprises an outer plunger (13) forming a first reservoir (20), a

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hydraulic orifice (17) sized to prevent escape of the hydraulic fluid from the first reservoir by capillary action, and an inner plunger (12) positioned within the outer plunger, the inner plunger being positioned and configured such that as the drive mechanism operates (arrow in Fig. 2d) the inner plunger (portion 18 of inner plunger) acts against the hydraulic fluid (acts against the driving mechanism's pressure and hence the pressure exerted by the fluid in the opposite direction of the arrow) and the hydraulic fluid is expelled from the first reservoir through the hydraulic orifice (Fig. 2d, fluid leaves through element 17 as designated in Fig. 2b). Antoshkiw further discloses a second reservoir (channel in Fig. 2d designated as 17) configured to contain the hydraulic fluid expelled from the first reservoir (col. 2, lines 52-60). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jeffrey with the compound plunger and reservoir as taught by Antoshkiw, in order to provide an injection device that allows for more control of the exposure of the syringe as well as to allow for more control of how the medicament is injected.

Allowable Subject Matter

Claims 3-6, 14-18 and 26-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 37 is allowed as the second reservoir, configured to contain the hydraulic fluid expelled from the first reservoir wherein the second reservoir is formed between an outer surface of the outer plunger and an inner surface of the syringe cartridge, distinguishes the claimed device over prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Merin C. Surmons